The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

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BOARD OF PATENT APPEALS
AND INTERFERENCES

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte WALTER L. MILLER, JOSEPH A. MARTIAL, and JOHN D. BAXTER

Appeal No. 1998-1851
Application No. 08/487,312

HEARING: December 10, 2002

Before WILLIAM F. SMITH, LORIN, and ADAMS, Administrative Patent Judges.

LORIN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 19-22, all the claims pending in the application.[1]

[1] Pursuant to 35 U.S.C. § 6(b), we review the adverse decision of the examiner. In doing so, we have considered the record, including:

- Final Rejection (paper no. 11);
- Advisory Action (paper no. 14);
- Brief (paper no. 16);
- Examiner's Answer (paper no. 17); and,
- Reply Brief (paper no. 18).

Claim 19, the sole independent claim, is illustrative of the claims on appeal and reads as follows:

19. Bovine growth hormone produced by a method which comprises culturing cells which contain a recombinant DNA molecule which DNA molecule comprises a nucleotide sequence encoding bovine growth hormone comprising the amino acid sequence at positions 2-191 of Figure 1 or an allelic variant thereof, said encoding nucleotide sequence contained in an expression system effective in producing said encoded bovine growth hormone in a recombinant host cell,

said culturing under conditions wherein the encoding nucleotide sequence is expressed to produce said bovine growth hormone; and

recovering the bovine growth hormone from the culture.

The reference relied upon by the examiner is:

Daniels et al. (Daniels)	3,265,579	Aug. 9, 1966

Claims 19-22 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as being obvious over Daniels.

For the purpose of deciding this appeal and consistent with the parties' statements that the claims stand or fall together (see Examiner's Answer, p. 3; Brief, p. 3), our discussion will focus on claim 19.

BACKGROUND

As a matter of background, this application (08/487,312) is a continuation of parent application 07/480,745 which was involved in Interference No. 103,925[2]. In that interference, there was a single count to a method of recombinantly producing bovine growth hormone (bgh) - a polypeptide that is

[2] Judgment awarded to appellants (Miller et al.). Appellants were determined to be entitled to the claims designated to correspond to the count.

secreted by the pituitary gland and which can be administered to young cattle to increase their growth rate and weight gain. The claims (claims 31-32, 34-35, 37-38, 40-41 and 57) in the parent application which were designated to correspond to the count were directed to:

- a recombinant DNA molecule comprising a segment encoding bgh;
- a composition of DNA molecules encoding bgh;
- a microorganism transformed with the recombinant DNA molecule encoding bgh;
- a method to produce bgh comprising culturing a microorganism transformed with the recombinant DNA molecule encoding bgh and recovering the bgh; and,
- a method to produce bgh from a recombinant DNA vector.

Neither the count nor the claims designated to correspond to the count were directed to bgh itself. That is the subject matter of this appeal.

DISCUSSION

The facts are as follows:

- The claimed subject matter is directed to "[bgh] produced by a [recombinant] method ... ."
- The claims lack physical description. Only process limitations are recited. Accordingly, the claims are constructed in product-by-process format.
- The claims have been rejected over Daniels under anticipation and obviousness grounds.
- Daniels (e.g., col. 1, line 25) teaches bgh.
- In contrast to the recombinant process by which the claimed bgh is made, the Daniels bgh is extracted from pituitary glands and then purified.

- Examiner has taken the position that Daniels' bgh "appears to be substantially the same"[3] as the claimed bgh.

Our initial inquiry is whether the examiner's prima facie determination of unpatentability is a sound one. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See also In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) ["where the claimed and prior art products are ... substantially identical ... the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product."].

It is axiomatic that the patentability of a product-by-process claim does not depend on the process limitations recited in the claim but on the characteristics of the product, In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)[4].

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[3] "The instant claims encompass bovine growth hormone. Daniels et al. disclose bovine growth hormone which is purified from a tissue source. (See examples 1-6, columns 2-4, especially example 6.) The bovine growth hormone disclosed in the prior art of Daniels et al. appears to be substantially the same as that of the instant claims, wherein such was isolated from bovine tissue, versus the claimed bovine growth hormone that was produced by recombinant techniques." Examiner's Answer, pp. 2-3.

[4] "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

As we have already indicated as a fact, there are no product characteristics recited in the claims. Appellants place a great emphasis on the recited process limitations as necessarily providing the product with properties that cause it to be distinguishable from the prior art. But, while the process limitations in the claim may be considered to the extent that they imply that the product would necessarily possess certain characteristics, as a practical matter, the Patent Office is not equipped to conduct the steps of the process recited in a product-by-process claim in order to determine whether the product exhibits certain characteristics not exhibited by prior art products as a direct result of what may arguably be a unique manufacturing procedure. See In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

That being said, there is nothing on the record from which the examiner could reasonably be expected to conclude that the process steps in the claim, albeit new in the art, necessarily confer characteristics to the resulting product that would render it different in kind from that described in Daniels.[5]

Take appellants' specification for example. The Background of the Invention (pp. 1-3) discusses the uses and consequences of administering conventionally-produced bgh based on its known properties[6], such as increasing

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[5] Compare In re Fessman, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974): "However, there is nothing in the record before the examiner from which he could reasonably have been expected to conclude that appellant's composition differs in kind from those obtained by other inventors solely because it was derived from a process not known to the prior art."

[6] E.g., "Uses of bovine growth hormone are based on its known biological activity described above." Specification, p. 1.

the rate of growth of cattle. The rest of the specification discusses the bgh DNA, the encoded bgh protein, its coding sequence, and procedures to isolate the DNA and express the bgh protein, buttressed by four examples, variously directed to synthesizing the cDNAs of bovine growth pre-hormone and bgh, sequence analysis and the expression of bgh. All that we are told is that the bgh is a recombinant product, has a particular amino acid sequence, and has the capacity to, for example, increase the rate of a cattle's growth. But, there is no suggestion that a recombinant bgh is in any way different from its natural counterpart by virtue of it being the result of recombinant technology. And the amino acid sequence and the capacity to be used, for example, to increase the rate of a cattle's growth, are properties it shares equally with Daniels. Other than that, the specification is silent.

Therefore, we find that there is nothing in the claims and specification that the examiner could have relied upon that would have led her to conclude that the claimed recombinant bgh is in any way different from that of Daniels. Accordingly, in our view, the examiner has shown a sound basis for believing that the Daniels' bgh is substantially the same as the claimed bgh. Because of the paucity of descriptive information, both in the claims and in light of the specification, the examiner reasonably determined that the claimed bgh is substantially the same as Daniels' bgh. Accordingly, we find that the prima facie determination that the claimed subject matter is anticipated and/or obvious over Daniels is a sound one and, thus, the burden now shifts to appellants to rebut

the prima facie case by showing that the claimed subject matter patentably distinguishes from Daniels.

Appellants have put forward an argument which asserts that the claimed bgh possesses, inherently, certain characteristics that distinguish it from Daniels. As we understand it, appellants are relying on the following two characteristics in support of their position that the claimed bgh is inherently different in kind from the bgh that Daniels produces:

1. its recombinant aspect; and,
2. as a direct result of the recombinant aspect, the guarantee of freedom from the causative agent for Mad Cow Disease (MCD).

As we will now explain, we find appellants' argument unpersuasive.

Initially, we observe that this argument which asserts that the claimed bgh necessarily distinguishes from Daniels is not supported by any declaration/affidavit; for instance, there is no evidence that an experiment was performed to determine the difference in properties between the claimed bgh and that of Daniels. Appellants could have presented data comparing the results of using the recombinant bgh in fattening cattle as opposed to using the bgh of Daniels. It would seem that the simplest and best course of action would have been to conduct such an experiment whereby the properties of a recombinant bgh are compared to those of an extracted and purified bgh and to rely on the results to then make the case that the claimed bgh is in fact unexpectedly different in kind from Daniels. But that has not been done. We are left to decide

whether appellants have satisfied their burden of rebutting the prima facie case, not based on the persuasiveness of any comparative data, but on the relative strength of their argument that the claimed product does in fact have distinguishing characteristics.[7]

Recombinant Aspect

Appellants contend that there is no question that the claimed and Daniels' bgh's are not substantially identical because the claimed bgh is a product of a recombinant method and the Daniels' bgh is not.[8] In point of fact, there is such a question.

There is no dispute that the claimed bgh is recombinant, given that it is the result of a recombinant process. And there is no dispute that the Daniels' bgh

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[7] Apparently mindful that argument alone would not be a persuasive showing of unexpected results (i.e., "It is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice." In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984)), appellants (footnote 3 of the Reply Brief) note that although the dispositive issue is one of unexpected results, "unexpected" is not appropriate here. "It is recognized that recombinantly produced bovine growth hormone is not expected to be contaminated with the causative agent for mad cow disease. However, it is only through appellants' invention that a composition thus free is available." In other words, we are to take the characteristics of being recombinant and guaranteed free of the causative agent of MCD as something "expected." Presumably if they were expected, there would be no need to prove it. In any event, it is appellants' burden to prove that these characteristics describe the claimed bgh and that they cause the claimed bgh to distinguish it in kind from Daniels. And that proof would have been better demonstrated with factual evidence, not argument.

[8] See Footnote 2 of appellants' Reply Brief, in its entirety: "There is no question that Daniels' product and the product of the invention are not identical, even if a host cell were used that effected posttranslational modifications equivalent to those existing in Daniels' product. This is because products purified to apparent homogeneity still contain small amounts of impurities that are undetectable by whatever methods are currently available. These impurities will be different

is not a recombinant product. The dispute is over the significance of saying that appellants' bgh is recombinant and Daniels' bgh is not and whether that difference in labels translates into a patentably significant difference in characteristics, so much so that it patentably distinguishes the claimed bgh from Daniels. In this case, where we have been given no explicit evidence of any characteristic[9] that would be conferred to bgh by virtue of it being produced recombinantly, we cannot then say that the claimed bgh is any different from Daniels.

We do not dispute that a difference exists between conducting a recombinant technique and one involving extraction and purification as Daniels describes. But that is not the issue here. The question to be determined is whether examiner properly determined that the claimed subject matter is substantially identical to that of the prior art and, if so – which is the case here, whether appellants have shown otherwise. Therefore we must look to the products and, in that regard, the issue reduces to an evaluation of the differences in the characteristics of these products. It is appellants' burden to show a difference, if one exists, between its recombinant product and that of

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for Daniels' products isolated from pituitaries as compared to those in recombinantly produced bovine growth hormone produced in other cells."

[9] Appellants do argue that the claimed bgh is guaranteed free of the causative agent for MCD but there is no explicit evidence of this. See discussion infra under the next heading.

Daniels. But, in fact, appellants have not done so.[10] We have not been provided with any showing that, for example, compares the properties of appellant's recombinant bgh and Daniels' conventionally-obtained bgh. As we stated earlier, it would have been a simple matter to comparatively test the properties of these products. But that was not done. Nor are we directed to anything in the disclosure that would suggest that a difference in properties actually exists. Not a single characteristic, in either the claims or the specification, or through objective evidence, indicating that the result obtained from a recombinant technique possesses properties that would distinguish it from that obtained by conventional means, has been provided. We can point to nothing which would lead us to say that the evidence weighs in favor of appellants argument that the claimed bgh is patentably different from Daniels by virtue of its recombinant nature.

Appellants seemingly suggest that the court has entertained the view that a "recombinant" product is per se different from a non-recombinant one, much like a "synthetic" product is necessarily different from a natural one. Appellants mention the following decisions:

- In re Wakefield, 164 USPQ 636 F.2d (CCPA 1970) [Wakefield];
- Amgen, Inc. v. Chugai Pharmaceutical Co., 9 USPQ2d 1833 F.2d (Fed. Cir. 1989) [Amgen];

[10] "The compositions of Daniels are unlikely to be structurally identical to the compositions of the present claims, but appellants have not adduced experimental evidence to demonstrate this." Brief, p. 6.

- Scripps Clinic & Research Foundation v. Genentech Inc., 927 F.2d 1565, 18 USPQ 2d 1010 (Fed. Cir. 1991) [Scripps];

- Atlantic Thermoplastics Co., Inc. v. Faytex Corp., 5 F.3d 1477, 28 USPQ2d 1343 (Fed. Cir. 1993) [Atlantic I] and 970 F.2d 834, 23 USPQ2d 1481 (Fed. Cir. 1992) [Atlantic II]; and,

We have carefully reviewed these decisions. None of these decisions advocate the suggested point of view. Nowhere does the court hold that a recombinant product is per se patentable over its natural counterpart. The court has oft-stated that there are no per se rules and none of these cases are contrary to the well-accepted principle that each case is decided on its own facts.

In Wakefield, the court construed the term "synthetic," used in the claims to describe the claimed rubber, as precluding natural rubber from which impurities have been removed. To reach that construction, the court considered the dictionary meaning of "synthetic," the interpretation given to the term "synthetic" by those of ordinary skill in the art – as demonstrated by the "Horne" patent, and consulted the preliminary portions of applicant's specification which "draws a sharp and consistent distinction between synthetic rubbers on the one hand and products made from natural rubber on the other" (at 164 USPQ 641). In other words, the court did not presume that "synthetic" and "natural" are necessarily different, but looked to and was persuaded by the evidence in support of that difference. There the evidence supported a distinction. We contrast Wakefield with the facts in this case. Here there is no evidence of a distinction between a recombinant bgh and a purified natural one. While, we

repeat, it goes without saying that recombinant processes are different from conventional ones, appellants do not point us to any dictionary, patent, portions of the specification, or any other publication or objective evidence showing that a difference necessarily exists between a protein produced recombinantly and the same one produced naturally.

Appellants (Brief, p. 4) stress that the court in Wakefield found that a conclusion of obviousness would be rebutted where, at the time the invention was made, no known or obvious method of making the claimed composition existed and that, in this case, appellants have received indication that the method by which the claimed bgh is made is allowable (see supra) and thus no method of making it was previously known. Suffice it to say that we do not see Wakefield the same way. That a previously unknown process was used to make it is a factor to be considered, especially where the manufacturing steps confer a characteristic to the product that it could not otherwise obtain, but it is not determinative of the patentability of the resulting product and Wakefield does not say otherwise. We know of no case that holds that the result of patentable manufacturing process is itself always patentable. After all, "[i]f the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

We need not address Amgen because, although appellants raise it, appellants nevertheless admit that it is not germane to the facts in this case.

Regarding Scripps, we note that appellants specifically draw our attention to page 1016 which, according to appellants, "holds that claims to Factor VIII prepared by a particular purification process would be infringed by recombinantly produced Factor VIII." As appellants concede, this clearly conflicts with appellants' argument that a recombinant protein is per se patentably distinct from its natural counterpart. However, we do not agree that this decision in any way complicates resolution of the matter before us and that we are forced to reconcile the holding in this decision with the other ones cited, notably Wakefield, in order to decide this appeal. Scripps treats product-by-process claims consistent with other court decisions. The reason the Scripps court reaches its decision is not because of any change in perspective about product-by-process claims but because the evidence supported a different conclusion. The court's reliance on the evidence is key. We reproduce a short section of that discussion:

> Genentech argues that its product is equitably seen as changed 'in principle', particularly when viewed in the context of the prior art. Genentech asserts that the specific activities and purity that are obtainable by recombinant technology exceed those available by the Scripps process [using plasma] ... which if found to be correct could provide – depending on the specific facts of similarities and differences – sufficient ground for invoking the reverse doctrine ... the issues raised by new technologies require considered analysis. ... Consideration of extrinsic evidence is required.

At 18 USPQ2d 1014. Same as in the other cases appellants cite, Scripps turns on the evidence. Scripps does not support the view that a recombinant product is per se patentably different from a natural one.

Regarding Atlantic, an extensive discussion about product-by-process claims, including a historical background, is provided starting at 23 USPQ2d 1484 of Atlantic II. The court states that a product-by-process claim can rely on the characteristics derived from the process by which it is made as an alternative to describing the product in more conventional terms and holds, in cases of infringement analyses in particular, that process limitations cannot be ignored. However, nowhere in this decision is there any per se rule that a product produced synthetically automatically renders that product patentable over its natural counterpart. Nowhere does it suggest that a product made by recombinant means is necessarily different from a prior art product that was produced under more conventional conditions.

In addition appellants cite Ex parte Gray, 10 USPQ2d 1922 (BPAI 1989) [Gray]. We need not address Gray. Although the facts in that case are very similar and we reach herein the same decision, it is not legal precedent. Nevertheless, we note, consistent with the other decisions, no per se rule was applied.

Accordingly, we have reviewed the decisions that appellants have raised in their brief and reply brief and find that they do not support the view that, absent any supporting evidence, a recombinantly-produced protein is necessarily

patentably different from its natural counterpart. To the extent that appellants are urging that we find a patentable distinction by virtue of the recombinant nature of the claimed bgh, we decline to do so. As we have indicated, there is no dispute that there is a difference between the step of recombinantly producing a protein and Daniels' conventional steps of extracting and purifying. But the difference in results is not at all clear. Here, where there is an absence of evidence of any distinguishing characteristic or property, we cannot say that the recombinant means of production conveys a property to the resulting bgh that is per se not exhibited by its natural counterpart in Daniels.

Accordingly, appellants have not satisfied their burden of overcoming the prima facie case of unpatentability on the ground that the claimed bgh is per se recombinant and Daniels is not.

Guarantee Of Freedom From The Causative Agent For MCD

Appellants also contend that, as a direct and unique result of the recombinant technique used to make it, the claimed bgh has the characteristic of being guaranteed free of the causative agent for MCD ("Mad Cow Disease," also known as bovine spongiform encephalopathy (BSE))." According to appellants, "[i]t is this guarantee that makes for the patentable distinction," Brief, p. 7.[11]

[11] We will assume arguendo, for purposes of deciding this appeal, that a guarantee is, per se, a property on which appellants can rely to show a patentable distinction. The issue of whether a "guarantee" constitutes a product property was the subject of a good deal of debate between appellants and the examiner. According to the examiner (Answer, p. 8), "[a]bsolute guarantees are not the standard of patentability," while appellants (Reply Brief, p. 3) have stated that they "do not believe that this issue as it applies to patent law has been adjudicated." We need not address

Assuming arguendo that appellants are correct in their assumption that the claimed bgh would in fact be free of the causative agent for MCD,[12] nevertheless it does not represent a patentable distinction over Daniels.[13]

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this issue to reach a decision and therefore we will not attempt to resolve the issue, if in fact one exists.

[12] This assumption is arguable. In keeping with our earlier comment that we have not been provided with any objective evidence of a difference between the claimed bgh and that of Daniels, we point out here also that appellants have submitted not one piece of evidence in support of the "warranty" distinction they assert renders the claimed subject matter patentable over Daniels. Notwithstanding the argument that there is such a distinction, there is no evidence that a recombinant bgh is always guaranteed free and a naturally-produced bgh is never guaranteed free of the causative agent of BSE. Neither bgh has been tested for the presence of a causative agent for Mad Cow Disease or the potential to carry it and no document has been presented to establish that a recombinant procedure – as opposed to an extraction/purification procedure - necessarily confers a characteristic to the recombinant bgh that allows it to preclude, in all cases, the presence of any causative agent for Mad Cow Disease. Furthermopre, we have read footnote 1 of the Reply Brief wherein appellants state that "[i]f the causative agent is a prion, the absence of any virus is irrelevant. There is no concern regarding this matter in connection with the administration of recombinant bovine growth hormone. See the enclosed article by Juskevich, J.C. et al. Science (1990) 249:875-849 [sic: 883] which reports FDA's evaluation of the safety of recombinant bovine growth hormone." However, nowhere in this reference can we find any mention that the recombinant bgh is considered guaranteed free of the causative agent for MCD and appellants do not point us to any such disclosure. Notwithstanding the FDA imprimatur of the product's current safety, the possible future presence of a causative agent for MCD appears to be a matter of speculation.

[13] While raised as indicative of a patentable distinction, it is important to point out that the warranty of freedom from the causative agent for MCD is an undisclosed property which does not appear to inherently flow from anything disclosed in the specification. As the examiner has observed (Answer, p. 4), the property of being guaranteed free of the causative agent for BSE is nowhere mentioned in the specification. That this property is not explicitly disclosed is not in dispute. Therefore it is reasonable to say that appellants' argument is based on an undisclosed property. In that regard, appellants (Brief, p. 7) say that "[t]his advantage [i.e., a warranty of freedom from the causative agent for BSE] is inherent in the description in the specification wherein the use of the claimed product is to stimulate the growth of cattle (see pages 1-2, bridging paragraph)," and then and rely on In re Chu, 36 USPQ2d 1089 (Fed. Cir. 1995), to argue that this "freedom," though undisclosed, need not be set forth in haec verba in the specification. While it is clear that a verbatim disclosure of a property of being guaranteed free from the causative agent for MCD is not necessary but where an applicant relies on an undisclosed property for showing patentability, the undisclosed property must flow inherently from something else in the specification. In re Davies, 475 F.2d 667, 177 USPQ 381, 384-385 (CCPA 1973). Appellants direct us to a passage in the Background about using bgh to stimulate cattle growth. But we fail to see how this gives any indication that the claimed bgh exhibits the guaranty to be free from the causative agent for a disease, let alone MCD. We are given no other information that would help us make the link between growing cattle and that guarantee. We have considered

Daniels encompasses a broad range of purified bgh products. The purification step taught therein leads to a bgh with a purity that would fall within a broad range of purities, from less than 100% of the original amount of impurities to potentially 0%. Examiner has pointed out, and it is not disputed, that Daniels (col. 4, lines 33-37) discloses a chromatogram of the purified bgh that reveals a single peak. This suggests that the method of Daniels is capable of producing an extremely pure bgh, potentially having 0% impurities.

While it is not entirely clear what the causative agent for MCD is[14], if we assume that one source for the causative agent is the pituitary gland of an MCD-infected cow, it might be possible that a bgh extract obtained by way of Daniels'

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the Washington Post article ("FDA Moves on 'Mad Cow' Disease Rules") attached to Appellants' Amendment of January 17, 1997, paper no. 13. Based on the article, we do understand that it is well known that Mad Cow Disease is a disease to be prevented and that it is a disease which spreads rapidly through feed products, especially where the feed is manufactured from the carcasses of animals infected with the disease, but the nexus between the disclosure of stimulating cattle growth with bgh and a stipulation that the recombinant bgh in fact possesses the property of being guaranteed free of the causative agent for MCD, even in light of what is known about the disease and how to prevent it, is impossible to ascertain. For that reason, "[appellants do] not [appear to be] in a favorable position to urge [the guarantee] as a basis for the allowance of claims." In re Lundberg, 253 F.2d 244, 117 USPQ 190, 192 (CCPA 1958).

[14] During prosecution examiner (Final rejection, paper no. 11, p. 4) considered the causative agent for MCD to be a virus (relying on statements made in Science, Vol. 228, 1985). To which appellants (Brief, p. 6-7) replied: "it is not clear that BSE is, indeed, caused by a virus and the nature of the causative agent is not known." Appellants (p. 3 of Amendment, paper no. 13) advocated instead the belief that BSE was caused by prions, relying on a study involving the similar Creutzfeldt-Jakob disease:

> In the later article in Science, also included with the previous response, Science (1991) 252:1515-1522, Stanley Prusiner describes BSE and Creutzfeldt-Jakob disease (CJD) as well as kuru as caused by prions rather than viruses. There is still evidently some controversy over the causative agent; nevertheless, there is now considerable evidence that all of these diseases, including scrapie, are caused not by viruses but by prions.

But now in the brief (p. 7), appellants site an article in BioWorld Today (January 17, 1997, p. 1) entitled "Mice Inoculated with Infectious 'Mad Cow' Brain Tissue Belie Accepted Prion Wisdom" and say that it "is clear from this article that the nature of the causative agent is still unknown." It would appear that appellants concede that the nature of the causative agent for MCD is unknown.

method would contain the causative agent. But this is all speculation on the part of appellants. Again, the precise nature of the causative agent is unknown. Furthermore, without knowing the nature of the causative agent, it is impossible to determine whether Daniels' method would remove the causative agent.

We understand that appellants are contending that the claims bgh possesses the guarantee of future freedom from the causative agent for BSE, not merely the present manifestation of the freedom itself.[15] Appellants are not arguing that they have met their burden of overcoming the prima facie case on the grounds that the claimed bgh is merely free from the causative agent for BSE but rather that the claimed bgh possesses a warranty of freedom from the causative agent for MCD and that it is possession of that warranty which patentably distinguishes it from Daniels' bgh. But this does not change our view that the claimed subject matter reads on Daniels

We have considered appellants' argument (brief, p. 5) that "FDA is prohibiting the use of animal proteins in feed to prevent any possible transmission of [MCD], regardless of the fact that it has not so far been detected." To that we respond by saying that we are not in a position to judge whether Daniels' bgh is recognized as unsafe to use since the alleged FDA regulation prohibiting the use of animal proteins, like bgh, has not been

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[15] In fact appellants (Brief, p. 4) concede "that it is quite unlikely that the actual material [extracted/purified bgh] exemplified in the Daniels patent contained this agent [i.e., for BSE]." As the examiner (Final rejection, p. 4) has previously observed, there has never been a case of Mad Cow Disease in the United States and therefore one of ordinary skill would have every expectation that the Daniels bgh is equally free of the causative agent for MCD.

supplied[16]. Even if it were true that the FDA has prohibited the use of bgh, it would nevertheless be a cautionary measure and not indicative of any potential safety problem with using the Daniels product.

Accordingly, notwithstanding appellants' emphasis that the claimed bgh has a warranty of freedom from the causative agent for MCD, this is something that Daniels' would also encompass. We do not find that the asserted warranty constitutes a patentable distinction over Daniels.

Accordingly, we find that the prima facie determination that the claimed subject matter is anticipated and/or obvious over Daniels remains a sound one and that appellants have not satisfied their burden of rebutting the prima facie case by showing that the claimed subject matter patentably distinguishes from Daniels.

[16] Appellants submit that the FDA has ruled against the use of extracted bgh but relies on statements made in a Washington Post article published June 4, 1997 (attached to the Brief).

The rejection under 35 U.S.C. § 102/103 is AFFIRMED.

No time period for taking any subsequent action in connection with the appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

WILLIAM F. SMITH)
Administrative Patent Judge)
)
)
) BOARD OF PATENT
HUBERT C. LORIN)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
DONALD E. ADAMS)
Administrative Patent Judge)

Setting aside the hearsay quality of this evidence, it is not clear whether the FDA regulation is still in effect or, if it still is, whether the prohibition covers growth hormones.